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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
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Additional inventors are being named on the _____ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Fluid composition used to simulate human synovial fluid

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 9
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☐ Application Data Sheet. See 37 CFR 1.76

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☑ Applicant claims small entity status. See 37 CFR 1.27.
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Respectfully submitted,

SIGNATURE _____ Date February 12, 2004

TYPED or PRINTED NAME Matthew J. Raymond REGISTRATION NO. 45,035 *(if appropriate)*

TELEPHONE 312-563-2780 Docket Number: R207

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TITLE

Fluid composition used to simulate human synovial fluid

FIELD OF THE INVENTION

The present invention relates to a fluid composition used to simulate human synovial fluid in the tribological analysis of artificial joints. More specifically, the invention relates to a fluid composition used to simulate synovial fluid which generates wear properties similar to human synovial fluid (involved in the tribological analysis of artificial joints).

BACKGROUND OF THE INVENTION

In-vitro evaluation of implant performance is a standard practice in the design, development, and manufacture of artificial hip and knee joints. In order to obtain clinically relevant results from such tests, it is essential to simulate the in-vivo joint conditions as closely as possible. Such joint conditions include the applied loads, moments and displacements, the temperature, and the surrounding media present in the joint. Fluid compositions to be used during in-vitro testing are commonly produced for the purpose of simulating the human synovial fluid that naturally surrounds the joint in-vivo. Various studies show the significant influence of chemical and physical parameters of testing fluid in the wear outcome in joint material testing. The fluid composition embodied by the present invention has been demonstrated to appropriately approximate human synovial fluid while also generating clinically relevant results. These and other

objects and advantages of the present invention, as well as additional inventive features, will be apparent from the description of the invention provided herein.

SUMMARY OF THE INVENTION

It is the object of the present invention to provide a fluid composition to be used in simulating human synovial fluid during the tribological analysis of artificial joints.

It is another object of the present invention to provide a fluid composition possessing a minimal influence on wear properties involved in the tribological analysis of artificial joints.

The present invention relates to a fluid composition comprising a serum, a synthetic amino acid, and water. In one aspect of the present invention, it is contemplated that the serum of the fluid composition is bovine calf serum. It is further contemplated that the synthetic amino acid of the fluid composition comprises Ethylene-Diamine-Tetra-Acetate.

In another aspect the present invention relates to a fluid composition comprising a serum, a fungicide and/or herbicide, and water. In one aspect of the present invention, it is contemplated that the serum of the fluid composition is bovine calf serum. It is further contemplated that the antibiotic solution of the fluid composition comprises Sodium Azide. In this aspect, it is still further contemplated that the fluid composition might

additionally comprise a synthetic amino acid. It is contemplated that the synthetic amino acid of the fluid composition is Ethylene-Diamine-Tetra-Acetate.

In another aspect the present invention relates to a fluid composition comprising a serum, an antibiotic solution, and water. It is further contemplated that the antibiotic solution of the fluid composition comprises Patricin. In this aspect, it is still further contemplated that the fluid composition might additionally comprise a synthetic amino acid. It is contemplated that the synthetic amino acid of the fluid composition is Ethylene-Diamine-Tetra-Acetate.

DETAILED DESCRIPTION OF THE INVENTION

The present invention encompasses a fluid composition comprising a serum, an antibiotic or fungicide/herbicide, a chelating agent, and water.

In a first preferred embodiment of the present invention, the serum of the fluid composition is bovine calf serum. In this embodiment, the chelating agent of the fluid composition comprises Ethylene-Diamine-Tetraacetic Acid (EDTA).

The second embodiment further encompasses the fluid composition consisting essentially of about 25.0% to about 99.8% bovine calf serum, about 0.1% to about 3.0% EDTA, and about 0.0% to about 67.0% deionized water, wherein the percentages of components are weight to weight of the fluid composition.

In a second preferred embodiment of the present invention, the serum of the fluid composition is bovine calf serum. In this embodiment, the fungicide and/or herbicide of the fluid composition comprises Sodium Azide.

In a third preferred embodiment of the present invention, the serum of the fluid composition is bovine calf serum. In this embodiment, the fungicide and/or herbicide solution of the fluid composition comprises Sodium Azide. In this embodiment, the fluid composition further comprises a synthetic amino acid. It is preferred that the chelating agent is EDTA.

The third embodiment further encompasses the fluid composition consisting essentially of about 25.0% to about 99.8% bovine calf serum, about 0.1% to about 5.0% Sodium Azide, about 0.1% to about 3.0% EDTA, and about 0.0% to about 67.0% deionized water, wherein the percentages of components are weight to weight of the fluid composition.

In a fourth preferred embodiment of the present invention, the serum of the fluid composition is bovine calf serum. In this embodiment, the antibiotic solution of the fluid composition comprises Patricin.

In a fifth preferred embodiment of the present invention, the serum of the fluid composition is bovine calf serum. In this embodiment, the antibiotic solution of the fluid

composition comprises Patricin A. In this embodiment, the fluid composition further comprises a chelating agent. It is preferred that the chelating agent is EDTA.

The fifth embodiment further encompasses the fluid composition consisting essentially of about 25.0% to about 98.0% bovine calf serum, about 0.1% to about 5.0% Patricin solution, about 0.1% to about 3.0% EDTA, and about 0.0% to about 67.0% deionized water, wherein the percentages of components are weight to weight of the fluid composition.

It is envisioned that alternative chelating compounds such as Ethylene Glycol bis (2-Aminoethyl Ether)-N,N,N',N'-Tetraacetic Acid (EGTA) or the sodium salts of EDTA can be substituted freely for the chelating agent described above. Likewise, many antibiotic and fungicide candidates exist which can be freely substituted for the described embodiments. Finally, the newborn calf serum can be replaced by serum from any available mammal, a number of manufacturers/retailers are available to purchase serum from alternatives such as horses, dogs, etc. The newborn calf serum can be replaced with fetal calf serum with a higher overall cost to the production.

While this invention has been described with an emphasis upon preferred embodiments, it will be obvious to those of ordinary skill in the art that variations of the preferred embodiments may be used and that it is intended that the invention may be practiced otherwise than as specifically described herein. Accordingly, this invention includes all

modifications encompassed within the spirit and scope of the invention as defined by the following claims.

EXAMPLE 1:

In this example, a solution is prepared for use in testing artificial hips. It is important to be consistent in preparing the solution for each use as batch to batch variability may impact test results.

The following materials are used in preparing the artificial synovial fluid. Each component is available from multiple commercial suppliers.

- Newborn Calf Serum
- Patricin A
- EDTA
- Deionized water
- Mixing cylinder (2l)
- Heating bath capable of reaching 50°C
- Magnetic stirrer and stir bar
- Filter unit 0.22µm
- Filter unit 0.45µm

The artificial synovial fluid is prepared as follows:

1. Pre-heat the frozen calf serum in water bath to 37-39°C
2. Fill mixing cylinder with amount of calf serum needed for the target volume according to the mixing ratios described herein
3. Add EDTA and Patricin A according to the mixing ratios described in Table 1.
4. Fill up the cylinder to the desired fluid amount
5. Mix the fluid (magnetic stirrer) for at least 15 min.
6. Filter the fluid first through the 0.22µm filter, then through the 0.45µm filter
7. Fill the fluid in squeeze bottle for use on simulator chambers

The fluid can be kept refrigerated for up to ten days.

300 ml of the fluid is then added to a Model HS2-12-1000, 12 Station Hip Simulator (AMTI-Boston) to test wear on artificial hips according to experimental protocols. Fluid is replaced in regular intervals of 1 to 3 days depending on the testing cycle.

Table 1. Mixing Ratios for Example 1

Final Vol [ml]	Serum [ml]	deionized water [ml]	EDTA [g]	Patricin [µg]
100	51.7	48.3	0.38	50
500	258.6	241.4	1.92	250
1000	517.2	482.8	3.85	500
2000	1034.5	965.5	7.70	1000

CLAIMS

I Claim:

1. A fluid composition used to simulate human synovial fluid in the tribological analysis of artificial joints, wherein the fluid composition comprises a serum, an antibiotic or fungicide and/or herbicide solution, and water.

2. The fluid composition of Claim 1, wherein the serum is bovine calf serum.

3. The fluid composition of Claim 1, wherein the fungicide and/or herbicide solution comprises Sodium Azide.

4. The fluid composition of Claim 1, wherein the antibiotic solution comprises Patricin A.

5. The fluid composition of Claim 1, further comprising a chelating agent.

6. The fluid composition of Claim 5 wherein the chelating agent is a synthetic amino acid.

7. The fluid composition of Claim 5, wherein the chelating agent is chosen from the group comprising Ethylene-Diamine-Tetraacetic Acid (EDTA), disodium EDTA, tetra sodium EDTA, and Ethylene Glycol bis (2-Aminoethyl Ether)-N,N,N',N'-Tetraacetic Acid (EGTA).

8. A fluid composition, consisting essentially of:

about 25.0% to about 99.9% bovine calf serum;

about 0.1% to about 3.0% Ethylene-Diamine-Tetra-Acetate; and

about 0.0% to about 72.0% deionized water,

wherein the percentages of components are weight to weight of the fluid composition.

9. A fluid composition, consisting essentially of:

about 25.0% to about 99.8% bovine calf serum;

about 0.1% to about 5.0% Sodium Azide solution;

about 0.1% to about 3.0% Ethylene-Diamine-Tetra-Acetate; and

about 0.0% to about 67.0% deionized water,

wherein the percentages of components are weight to weight of the fluid composition.

10. A fluid composition, consisting essentially of:

about 25.0% to about 99.8% bovine calf serum;

about 0.1% to about 5.0% Patricin A solution;

about 0.1% to about 3.0% Ethylene-Diamine-Tetra-Acetate; and

about 0.0% to about 67.0% deionized water,

wherein the percentages of components are weight to weight of the fluid composition.